

Applicant : Christos J. Petropoulos
Serial No.: 09/886,711
Filed : June 21, 2001
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Claims

The Examiner objected to claims 13 and 38 due to certain typographical errors.

In response, applicant notes that these typographical errors have been corrected in the claims as amended.

The Examiner objected to claim 55 as allegedly in improper dependent form.

In response, applicants note that claim 55 has been cancelled, making the objection thereof moot.

Claim Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-55 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, applicant respectfully traverses the Examiner's rejection.

The test for enablement is whether one skilled in the art could, at the time of the invention, make and use the claimed invention based on the disclosure and the information known in the art without undue experimentation. Applicant maintains that the claimed invention satisfies the test for enablement, and that the Examiner has not set forth sufficient grounds for concluding otherwise.

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Briefly, the rejected claims provide methods for producing hepadnavirus particles capable of infecting hepatic cell lines maintained *in vitro*. The present invention exploits similarities between the replication pathways of a hepadnavirus such as HBV and a foamy virus such as HFV, in order to circumvent obstacles that restrict hepadnavirus infection in cell culture systems. As such, these methods comprise, in relevant part, introducing into a host packaging cell an HBV genome expression vector and an HFV envelope expression vector. The resulting HFV pseudotyped HBV particles produced by the host packaging cells can then be harvested and used to inoculate target cells, thereby infecting the target cells with HBV.

In support of the rejection, the Examiner alleges that she was unable to find any prior art indicating successful pseudotyping of HBV with foamy virus envelope proteins. Moreover, the Examiner further alleges that the specification contains no working examples where cell culture-infectious HBV particles were actually produced. Therefore, the Examiner concludes that due to the unpredictability of success in producing an HBV pseudotype, an undue amount of experimentation would be required to make or use the invention.

Applicant disagrees with the Examiner's position. First, and as the Examiner concedes, applicant notes that at the time the application was filed, it was known that foamy virus envelope proteins could be used to pseudotype other types of retro viruses (Lindemann et al.). Moreover, the specification as filed teaches each and every step of the claimed methods. Such teaching can be found in the specification at, *inter alia*, page 39, line 10 to page 40, line 23. Therefore, the specification clearly sets forth applicant's invention based on the surprising discovery that foamy virus envelope proteins can be used to successfully

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pseudotype a hepadnavirus such as HBV. Hence, applicant maintains that the above teachings in the specification, coupled with what was known in the art at the time the application was filed, would clearly enable one skilled in the art to practice the claimed methods. Applicant notes that actual reduction to practice is not required for enablement.

Furthermore, under M.P.E.P. §2164.04, in order to make a rejection based on enablement, "the examiner has the initial burden to establish a *reasonable basis* to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562 (Fed Cir. 1993)." Applicant notes that the Examiner has failed to establish such reasonable basis. Specifically, the Examiner bases the rejection on the fact that a search of the prior art did not indicate successful pseudotyping of HBV. However, the Examiner omits citing any reference which teaches that HBV can not be successfully pseudotyped. Applicant respectfully submits that the mere absence in the art of an affirmative teaching of successful pseudotyping is not a reasonable basis for the Examiner's enablement rejection.

In view of the above remarks, applicant maintains that claims 1-55 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Summary

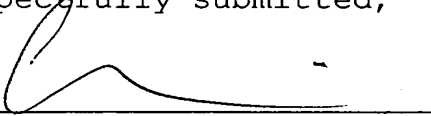
For the reasons set forth hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw the ground for rejection and earnestly solicits allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

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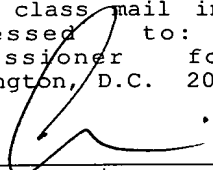
No fee, other than the enclosed \$460.00 for a three-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231.


Alan J. Morrison
Reg. No. 37,399

11/5/02
Date